Harmony Hill International Co., Ltd.

510(K) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: K123076 .

AUG 09 2013

Date of Summary prepared: July 22, 2013

1. Submission Correspondent: Harmony Hill International Co., Ltd.

   Address: Rm. 1068, 10F, H bldg. of NKSP, No. 3-2, Park St., Nangang Dist., Taipei, Taiwan

   Phone: +886-2-2655-7717

   Fax: +886-2-2655-7715

   Contact: Mrs Tina Lai

2. Submission Sponsor: Harmony Hill International Co., Ltd. Rm. 1068, 10F, H bldg. of NKSP, No. 3-2, Park St., Nangang Dist., Taipei, Taiwan
   Tel +886-2-2655-7717
   Fax +886-2-2655-7715
   E-mail tina@hhic.com.tw

3. Date Prepared: May 25, 2013

4. Trade Name(s): Profhand Pedal Wheelchair
   Models HM-10
   Common/Usual Name: Mechanical Wheelchair
   Classification Name: Wheelchair, Mechanical
   Classification Number: 890.3850
   Classification Panel: Physical Medicine Devices
   CDRH Product Code: IOR
   Regulatory Class: I

5. Device Description

   Profhand pedal wheelchair is manually driven, lightweight, performance type of wheelchairs that have been designed and developed to be used in both indoor and outdoor environments, and to transport one (1) person at a time

   For the main construction of HM-10 wheelchair, please see the following detailed description: The Chassis and pedaling mechanism are made form a aluminum alloy. Wheels are of a spoke and hub design using metal components and rubber tires, while the casters are of a semi-solid polymer base design. The seat cushion

and back are made from flame retardant Nylon and/or Polyester fabric.

The main operation of Profhand pedal wheelchair is as the following description (Note: This main operation can only be done under the instruction and permission of physician, so it is classified as a prescription device):

- Put a suitable seat cushion on the wheelchair seat.
- Put your foot into the pedal and attach the foot strap to stabilize foot.
- When riding use both legs to pedal for forward movement.
- To stop use the brake mounted in the control lever.
- For parking or getting on/off the wheelchair lock the brakes

In addition to the main operation as above mentioned, the Profhand pedal wheelchair also provide the handle bars in rear side of the chair to let healthcare person help moving the person who is seated on the wheelchair as the other general mechanical wheelchair.

6. Intended Use

Profhand pedal mechanical wheelchair is manually operated multifunctional wheelchairs designed for indoor/outdoor use and intended to provide mobility to persons that have the capability of operating a mechanical wheelchair.

7. Predicate Devices

Panthera Mechanical wheelchairs / Model S2 (K083231)

8. Safety and Effectiveness

By definition, the HM-10 device is substantially equivalent to a predicate device because the device has the same intended use and different technological characteristics. The main technology difference is that for our HM-10 wheelchair, the device provide mobility to person restricted to a sitting position either by attendant via using rear handle bar or by himself via using leg-pedaling mechanism, but for the predicate Panthera wheelchair, the device provide mobility to person restricted to a sitting position either by attendant via using rear handle bar or by himself via using hand-pedaling mechanism.

Through the rationale justification, it can be demonstrated that the device is as safe and effective as the predicate device and the new device does not raise different questions regarding safety and effectiveness as compared to the predicate device.

As such, it has been shown in this 510(K) submission, that the differences between the Profhand pedal wheelchair/Model HM-10 and the predicate devices, the Panthera Mechanical wheelchair (ref K083231), do not raise any questions regarding their safety and effectiveness.

9. Performance Date

Profhand pedal wheelchair/Model HM-10 have been designed, manufactured and tested for conformance to the relevant FDA recognized ISO standards for mechanical wheelchair as referenced in this submission. In addition, Profhand pedal wheelchairs passed all required consensus standards testing for conformance to the FDA's *Guidance Document for the Preparation of Premarket Notification [510(K)] Applications for Mechanical and Powered Wheelchairs, and Motonzed Three-Wheeled Vehicles.*

Compliance testing to FDA recognized standards includes the following list:

1. ISO 7176-1: 1999 – Determination of static stability.
2. ISO 7176-3; 2003 – Determination of effectiveness of brake.
3. ISO 7176-5; 2008 – Determination of overall dimensions, mass, and maneuvering space.
4. ISO 7176-11: 1992 – Test dummies.
5. ISO 7176-13; 1989 – Determination of coefficient of friction of test surface.
6. ISO 7176-15; 1996 – Requirement for information disclosure, documentation and labeling.
7. ISO 7176-16; 1997 – Resistance to ignition of upholstered parts.
8. ISO 10993-1; 2009- Guidance on selection of biocompatibility tests.
9. ISO 10993-5; 2009- Biocompatibility tests for cytotoxicity in vitro method.
10. ISO 10993-10; 2009 Biological tests for irritation and delayed-type hypersencitivity.

10. Conclusion

Profhand pedal wheelchair/Model HM-10 as designed and manufactured is as safe and effective as the predicate devices and therefore is determined to be substantially equivalent to the predicate devices, the Panthera Mechanical wheelchair (ref K083231).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

August 9, 2013

Harmony Hill International
c/o Ms.Tina Lai
Room 1068, 10F, H Bldg. of NKSP, NO.3-2
Park Street, Nangang Dist
Taipei
China (Taiwan) 11503

Re: K123076
Trade/Device Name: Profhand Pedal Wheelchair Model HM-10
Regulation Number: 21 CFR 890.3850
Regulation Name: Mechanical Wheelchair
Regulatory Class: Class I
Product Code: IOR
Dated: June 2, 2013
Received: June 5, 2013

Dear Ms. Tina Lai:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Joyce M. Whang -S

for Victor Krauthamer, Ph.D.
Acting Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K123076

Device Name: Profhand Pedal Wheelchair Model HM-10

Indications For Use:

Profhand pedal wheelchair is manually operated multifunctional wheelchairs designed for indoor/outdoor use and intended to provide mobility to persons that have the capability of operating a mechanical wheelchair.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Joyce M. Whang -S

(Division Sign Off)
Division of Neurological and Physical Medicine Devices (DNPMD)

510(k) Number K123076